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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09 494,088 | 04/28/2000 | Michael McGrogan | 001-060 HP | 3025 |

7590
04/29/2002
Barbara J. Luther
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| EXAMINER |
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BAKER, ANNE MARIE

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| ART UNIT | PAPER NUMBER |
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0632

DATE MAILED: 04/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary

Application No.

09/494.088

Applicant(s)

MCGROGAN ET AL

Examiner

Anne-Marie Baker, Ph D

Art Unit

1632

All participants (applicant, applicant's representative, PTO personnel):

(1) Anne-Marie Baker, Ph.D.

(3) _____

(2) Barbara Luther.

(4) _____

Date of Interview: 25 April 2002

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____

Claim(s) discussed: 1-17 and 19-22

Identification of prior art discussed: None

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See attached sheet

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04) If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135 (35 U.S.C. 132).

37 CFR § 1.2 Business to be transacted in writing

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiner's Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner.
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

The Examiner received and reviewed a faxed draft amendment and response prior to the telephone interview. Discussed the enablement rejection with regard to any gene therapy aspect of the claims. The Examiner clarified that she views the gene therapy rejection as a minor aspect of the rejection, but that the claims would cover using genetically modified progenitor cells as the starting material. The specification discusses the use of genetically engineered cells at several places, including for example at page 3, lines 10-11 and page 4, lines 10-15, where the specification discusses the transplantation of genetically engineered cells. The Examiner pointed out that the claim is very broad with respect to the progenitor cell, as it encompasses the use of any type of progenitor cell and thus, the claims cover the use of cells that have been genetically modified to express the various gene products recited in the claims. The Examiner suggested that they need to narrow the scope of the progenitor cell being used, at least to a neuronal progenitor cell. The Attorney agreed that they would likely amend the claim to recite a neuronal progenitor cell. The Examiner pointed out that the main problem with the case is that the specification teaches that the only use for the claimed method of producing cells is to provide cells for transplantation to produce a therapeutic effect, and therefore removing the intended use from the claim language does not obviate the rejection. Discussed Example 12 of the specification. The Examiner pointed out that there was no amelioration of clinical symptoms in the rats of Example 12, and that although there was a reduction in the rotational behavior of the rats as pointed out by Applicants at page 4, paragraph 2 of the draft response, the specification states, at the top of page 30, that this reduction was not statistically significant. The Examiner pointed out that, without further evidence to show that the cells produced by the claimed method could be used therapeutically in transplantation, that there was no enabled use for the cells. The Examiner suggested that Applicants need to provide further evidence or arguments to support an enabled use for the cells, or to correlate the properties/characteristics/phenotype of the cells to successful use in therapeutic transplantation. The Examiner acknowledges that fetal dopaminergic neurons have been used successfully in therapeutic transplantation, but that these fetal cells seem to have special properties that adult dopaminergic neurons and cell lines do not have that allows them to propagate and function after transplantation. The Attorney will take this into consideration and discuss with her clients to see if they can provide a correlation for successful use in therapeutic transplantation or other evidence that the cells produced would correlate to successful use in therapeutic transplantation. The Examiner pointed out that the method of producing the cells only has a use if the cells themselves have a use, but that only one enabled use in therapeutic transplantation is needed to enable the method of producing the cells, so long as it reasonably correlates to the scope of the claim. Here, the only use asserted in the specification is to use the cells in transplantation protocols for therapy. The Examiner also pointed to the "inhibitor" recited in step (c) of Claim 1 and suggested amending the claim to recite a mitotic inhibitor, as that is what the specification teaches, and it is unclear from the claim language what type of inhibitor is to be used. The Examiner also suggested that it may be helpful to re-word step (c) to make it clear that the step is intended to enrich for dopaminergic cells in the culture. The Attorney agreed that she will likely amend the claim to recite a mitotic inhibitor and clarifying claim language. The Attorney will take into consideration the matters discussed in preparing the response, and will further consult with her clients, possibly to prepare a Declaration.